

Docket No.: 30694/39646B  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
Giampiero De Luca

Application No.: 10/586,107

Confirmation No.: 1782

Filed: July 14, 2006

Art Unit: 1646

For: Methods And Compositions For The Treatment  
Of Lipodystrophy

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Examiner: G. Chandra

**RESPONSE TO RESTRICTION REQUIREMENT**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In response to the restriction requirement set forth in the Office Action mailed December 28, 2007, Applicant hereby provisionally elects the claims of Group I, i.e., claims 1-17, and further provisionally elects the species sulphonylurea, with traverse.

The claims of Group I are drawn to a method of treating a human suffering from an abnormal lipid distribution disorder, wherein the method comprises administering a growth hormone and a statin-based therapeutic agent. The claims of Group II are directed to a composition for treating abnormal lipid distribution disorders comprising a recombinant growth hormone and a statin-based therapeutic agent. Rule 13.2 PCT, on which the Office has relied, requires that there be a technical relationship among those inventions involving "one or more of the same or corresponding special technical features" in order to establish a single general inventive concept under Rule 13.1 PCT as required for unity of invention to be found. The Office concedes that the claims are united by the same technical feature, use of a growth hormone and a statin-based therapeutic to treat an abnormal lipid distribution disorder. However, the Office contends that the technical feature is not "special," citing International Patent Publication WO 00/23097 as assertedly teaching use of growth hormone


and statin to treat hypercholesterolemia. According to the Office, treatment of hypercholesterolemia is a treatment of an abnormal lipid distribution disorder. Applicant respectfully disagrees.

Treating hypercholesterolemia does not implicitly encompass treating abnormal lipid distribution disorders. Hypercholesterolemia is marked by elevated levels of total cholesterol in circulation. *See, e.g., Harrison's Principles of Internal Medicine* 2249 (Braunwald et al. eds., 15th ed., McGraw-Hill 2001). It is a metabolic abnormality associated with disordered lipid and/or glucose metabolism, as noted in the instant specification at, for example, page 8, lines 1-13. In contrast, lipid distribution disorders, e.g., lipodystrophy or obesity, are characterized by abnormal distributions and quantities of adipose tissue in the body. *Harrison's Principles of Internal Medicine* at 2316. Hypercholesterolemia may be a clinical manifestation of an abnormal lipid distribution disorder, but they are not the same disorder. *See* instant specification at, for example, page 8, lines 1-13. There is nothing in the cited reference that would suggest that hypercholesterolemia therapies would also be useful in treating lipid distribution disorders. Thus, the cited reference does not destroy the special technical feature establishing the general inventive concept linking Groups I and II, which represents an advance over the state of the art. Accordingly, the restriction requirement imposed for asserted lack of unity of invention should be withdrawn.

For the reasons stated above, Applicant respectfully requests that each of claims 1-20 presently pending in this application be examined.

Dated: January 24, 2008

Respectfully submitted,

By 

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